

# National Kidney Disease Education Program

## Defining Audiences:

### *Health Professionals and High Risk Groups*

## Meeting Summary

March 15 & 16, 2001

### Background

At the request of The Council of American Kidney Societies (CAKS), the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) addressed the need for a coordinated national program to strengthen efforts to prevent the morbidity and mortality of kidney disease. As a result, NIDDK is establishing the National Kidney Disease Education Program (NKDEP). Health problems that are a driving force behind this initiative include:

- A striking, steady increase in new cases of treated kidney failure over the past 2 decades;
- Markedly higher rates of cardiovascular disease in people with renal insufficiency and kidney failure;
- High rates of “late diagnosis” and, consequently, poor implementation of strategies to slow the progression of kidney disease and prepare for dialysis or transplantation; and
- Striking racial disparities in both the number of new cases of kidney disease and the provision of optimum care.

To address the request from CAKS and to insure the most effective use of NIH resources, NIDDK sought the advice of the Kidney Disease Education Task Force, a cadre of individuals with substantial expertise in health policy, education, and preventive medicine.

The Task Force met on July 18, 2000 and made the following recommendations:

1. Develop patient-centered messages that integrate strategies for reducing the risk of chronic illness.
2. Develop outreach programs for high-risk minority populations.
3. Develop new guidelines as appropriate.
4. Develop performance measures to track implementation of guidelines and methods to assess the effectiveness of outreach activities.
5. Develop science-based criteria to assess NKDEP.

“Defining Audiences: Health Professionals and High Risk Groups” meeting, summarized in this report, provided much of the data needed to start planning a kidney education program, including:

- Definition of high risk groups
- Information about how to reach high risk groups
- Optimal performance screening
- Optimal therapy
- Current practice and patterns of care
- Strategies for Change

A strategic planning meeting will convene on June 28<sup>th</sup> and 29<sup>th</sup> and include all interested constituent groups who can use the Final Report of the Task Force and the information from this meeting, along with an upcoming *Report on the State of Kidney Disease in the United States* to decide:

- How to educate and activate patients and the public; and
- How to educate and activate health professionals.

## Meeting Summary

The Director of NKDEP, Dr. Thomas Hostetter, opened the meeting and provided a brief history of the NKDEP to date. He stated that the need for NKDEP is based on:

1. The rising incidence of end-stage renal disease (ESRD) in the past few decades—doubling each decade; contrasted with
2. Evidence that good if not perfect therapy is available and is not being applied uniformly throughout the United States.

The Director, Division of Kidney, Urologic, & Hematologic Diseases, NIDDK, Dr. Josephine Briggs, encouraged meeting participants to consider what message would be appropriate for a NKDEP given the complex nature of kidney disease and treatment.

This summary provides a brief overview of each presentation.

## Session I: Definition of the High Risk Group

### Views from NHANES

Dr. Joe Coresh presented data from the NHANES III (1988-1994) to help participants consider what screening test or tests would most appropriately measure kidney function. Glomerular Filtration Rate (GFR) is an accepted measure of kidney function, but involves a formula that may prove too complicated to use in a health education campaign. Dr. Coresh suggested that equations using serum creatinine could be used to classify individuals with decreased GFR. The main problem with using creatinine level as a measure of kidney function is that there is enormous variation between calibrations across laboratories, creating as much as a 20-40 percent difference in readings.

The data suggest that using a serum creatinine level of 1.5 or more to identify individuals with a decrease in kidney function results in an estimated prevalence of 10 million people who have decreased kidney function in the United States. By using a serum creatinine level of 2.0 or more, the estimated prevalence is 5 million people.

Serum creatinine levels also can vary by gender, race, and with age. Serum creatinine levels are higher in African Americans than in whites and higher in men than in women. Dr. Coresh suggested that it would be appropriate to define reduced kidney function differently for each gender, 1.4 for women and 1.6 for men. Using this definition, there is an estimated prevalence of 5 million people in the United States with decreased kidney function. Although, many individuals within this group are already being treated for high blood pressure they have not yet reached a blood pressure level consistent with optimum kidney care (less than the usual 140/90 mm Hg).

Dr. Coresh also mentioned that a mild decrease in GFR might be a normal part of aging in the United States.

### *The Finer Scale Demography of Risk*

Dr. Neil Powe presented information compiled by linking the NHANES II ESRD Study (1976-1980) to the Medicare registry and the National Death Index through 1992. Dr. Powe analyzed the data to find factors responsible for increased risk of chronic kidney disease (CKD) and ESRD. This information will help NKDEP target education efforts to the most appropriate audiences and identify risk factors that can be influenced by behavior change.

Factors responsible for increased risk of CKD:

- Type 2 diabetes (women have greater risk than men)
- High blood pressure
- Physical inactivity
- High body mass index (BMI) or obesity (explained away if one considers blood pressure or diabetes)
- Smoking (greater than 20 cigarettes per day)
- Combination of smoking and inactivity (doubles the risk)
- Proteinuria (risk increases with the level of proteinuria—prevalence is greatest in people with diabetes and hypertension)

- Race (African Americans are more likely to develop CKD)
- Gender (women have a greater risk of CKD)

Alcohol was not a risk factor.

Overall lifetime risk of developing CKD is 8 to 9 percent.

A discussion about the validity of using proteinuria as a measure of kidney function followed the presentation. One advantage of a proteinuria dipstick test is that it would be low cost and simple. However, to date, no one has considered how many people would be falsely identified as having decreased kidney function.

### *The Characteristics and Geography of Risk*

Dr. Allan Collins displayed a number of maps depicting the incidence of diabetes, hypertension, ESRD, transplantation and other rare diseases across the United States. These maps identify geographic regions with high concentrations of target audience members and can be used to direct NKDEP efforts. He showed that new cases of ESRD due to:

- diabetes are in the Southwest (Hispanic population)
- hypertension are in the South
- cystic, heredity, and congenital kidney disease are in the West and Northwest
- pediatric hypertension are in the South

Dr. Collins reported that Hispanic populations are twice as likely to develop ESRD. Sixty percent of the ESRD in this population is related to diabetes.

### *Familial Links*

John Sedor presented information from the FIND Study (Family Investigation of Nephropathy and Diabetes) and the Cleveland ESRD Genetics Project showing that the following groups are at increased risk for ESRD:

- Family members of dialysis patients
- Diabetics with overt proteinuria
- Individuals who start dialysis at a young age
- Women

### *Discussion (Q&A)*

A discussion following the first session focused on who NKDEP should target and where to find target audience members. Suggestions included:

- ESRD/dialysis family members could be reached through the ESRD Networks
- The KEEP Program had an excellent turnout when first degree relatives were asked to participate in screening for CKD
- Provide screening as incentive (consider that some people may be scared away by racial or genetic issues, or fatalism and fear of the disease).
- American Indian Reservations

- Diabetes clinics
- Health Care Financing Administration (HCFA) Medicare Providers who care for high risk patients

Participants also discussed the extent to which lifestyle factors influence familial clustering. One participant mentioned a study with regard to proteinuria that suggested that 50-70 percent of one's risk is environmental and 30 percent is due to heredity.

Many other issues were mentioned during the discussion, including:

- Birthweight may also play a part in the risk for ESRD, but it is hard to develop a message based on that information.
- People in high-risk groups may avoid screening because they don't think there are any effective therapies or because they do not want to risk finding health insurance due to knowledge of a kidney problem.

Dr. Patel mentioned that the Veterans' Administration has guidelines for PCPs with regard to ESRD.

Participants suggested that the NKDEP message should be a hopeful message of prevention. It should include information about available intervention, and should not focus on genetics as a predictor of inevitability. The message for health care providers should include information about the risks of kidney disease and that kidney disease is a modifiable risk factor for ischemic heart disease, cancer, and other diseases.

## **Session 2: The Spectrum of Risk**

### *Case Finding Strategies for Individuals at Risk for ESRD*

Dr. Bill McClellan presented information about detection strategies. He compared screening success across a variety of settings, presenting the prevalence of individuals successfully identified by CKD screening as having reduced kidney function in each setting. Dr. McClellan reported a very low prevalence of kidney disease among the working population, but pointed out that this does not necessarily rule out work-site screening because screening has other purposes, such as patient, population, and provider education. CKD is more likely to be found in patients visiting their primary care physicians, the hospital, or the clinic. He suggested that it would be important for NKDEP to target high-risk populations based on geography, family history, or disease associated with ESRD and to identify prevalences that are consistent with need for an education program.

The data he presented also showed that in a random hospital chart review, Medicare patients with high blood pressure and diabetes were not receiving proper care (angiotensin converting enzyme (ACE) inhibitors or patient counseling/education) with regard to decreased kidney function. He suggested that changes in the systems of care might be necessary, including having the laboratories calculate and flag high creatinine levels.

## *The Results of KEEP Screening*

Dr. Wendy Brown, National Kidney Foundation, stressed the importance of educating both patients and health professionals to prevent kidney failure. Dr. Brown reported on research that has been done to assess the current level of knowledge among primary care physicians with regard to early intervention and prevention of renal disease. The survey showed that there is a tremendous variation in perception of patients at risk. Physicians reported that serum creatinine levels ranging from 1.5 to 10.0 mg/dL and that GFR less than 10 to less than 80 indicate chronic renal failure. Many doctors did not recognize that their patients were at risk for chronic renal failure.

Dr. Brown also reported on studies that have been done to screen and educate families of dialysis, hypertension, or diabetes patients. She believes that screening provides a powerful tool to access the target population. Once identified, patients and their physicians can be educated.

The Kidney Early Evaluation Program (KEEP 1.0) encouraged individuals deemed at increased risk to seek further evaluation from a physician and provided referral to a network of physicians who will take patients without insurance. The target audience included adults with hypertension or diabetes and adults who have a family member with hypertension, diabetes, and/or renal disease. The study was conducted in 21 pilot sites across the country. Seventy-three percent of those screened had one or more risk factors, the most common being hypertension. Of the 203 individuals who had abnormalities, diagnosis was only confirmed in 36.

Dr. Brown recommended that physician education be an integral part of NKDEP because many primary care physicians do not recognize the abnormality identified in the screen as a risk factor for renal failure.

The National Kidney Foundation also has KEEP 2.0, which screens in settings that are convenient for the target audience such as churches and Boys and Girls Clubs. In KEEP 2.0, 80 percent of those screened had one or more risk factors. KEEP 1.0 and KEEP 2.0 can be used as a model for ideas on how to reach the NKDEP target audiences.

## *Discussion*

A discussion followed and participants agreed that it would be important to involve primary care physicians and their associations in the planning of NKDEP. In KEEP 2.0, there was a tight link between positively screened patients and their physicians, so physicians would be prepared for patient interaction. Pharmaceutical companies also were involved in the physician education programs.

Dr. Kliger suggested that it is important to educate patients, so that they will go to the doctor if they have a positive screen for renal disease (40 percent do not follow up with a physician).

Another participant suggested that NKDEP should influence policy areas as well. For example, the HCFA's Diabetes Quality of Care Improvement project does not include a renal disease indicator.

### **Session 3: How Can High Risk Groups Be Reached?**

#### *Lessons from NDEP*

Associate Director of NKDEP Mimi Lising described the National Diabetes Education Program (NDEP), a public and private partnership effort to reduce the morbidity and mortality of diabetes and its complications. NDEP is co-sponsored by NIDDK and the Centers for Disease Control and Prevention in Atlanta. The primary message is “Diabetes is serious, it’s common, and it’s costly, yet it’s controllable.” The products are tailored to each target audience. The constituents help plan the program from beginning to end including, delineating roles for various workgroups.

Ms. Lising described each of NDEP’s five components:

- Special Populations
- Community Interventions
- Health Systems Improvements
- NDEP Partnership Network
- Evaluation

There are four different Minority Work Groups:

- African Americans
- Hispanics/Latinos
- Asian Americans/ and Pacific Islanders
- Native Americans

These groups provide guidance and assistance in campaign planning, materials development, dissemination and implementation, partner identification, and community interventions.

NDEP has developed tools and resources for communities such as the Community Partnership Guide that provides examples of activities one could do at the community level and also provides training and technical assistance to communities wishing to participate in diabetes education.

NDEP also focuses on health systems improvements and has developed a number of tools to help health care providers, such as “*Diabetes Numbers at a Glance*.” NDEP is launching a campaign for providers that focuses on comprehensive diabetes care. NDEP also has tools for businesses and managed care that focus on the economic consequences of diabetes.

NDEP Partners include more than 200 organizations that represent many constituencies. Partners incorporate NDEP messages and strategies into existing programs and activities that reach target audiences, especially underserved populations.

NDEP also has an evaluation workgroup that develops process and impact evaluation.

The most important lessons to NKDEP from NDEP are:

- Take time to develop relationships to establish trust and “buy-in.”
- Get input from partners in the beginning, middle, and end.
- Develop structure and roles for partners early in the planning process.
- Ask each organization to contribute at different levels depending on their expertise, commitment, and resources.
- Learn about each partner’s agenda, time frame, and expectations.

A discussion followed Ms. Lising presentation and several suggestions were made regarding the NKDEP, including:

- Build evaluation in from the very beginning.
- Use both process and outcome evaluation strategies.
- Define goals.
- Identify data sets and add questions that are relevant to NKDEP when possible.

### *Social Marketing*

Wendy Campbell presented an overview of social marketing principles. She defined social marketing as the application of marketing principles to social issues for the purpose of influencing and/or changing individual or group behavior. The process is methodical and includes evaluation and revision to ensure that the message is on target and behaviors are changing. The steps are:

1. Segment the audience by demographics such as age, income, education, geographic region, and marital status. Find out all you can about each segmented target audience group.
2. Define the problem. Discuss why the initiative is needed.
3. Assess the marketplace.
  - Identify and consult affinity groups—groups interested in kidney disease.
  - Analyze what is known about each segment of the target audience.
  - Assess existing programs—considering what is working and what is not working. Use what has been learned by NDEP.
4. Plan behavior goals. Decide what you want your audience to do and set specific, measurable and reasonable goals.
  - Influence beliefs.
  - Increase knowledge and skills.
  - Change and maintain specific behaviors.

Ms. Campbell also said to consider the four “P’s” of marketing:

- Price—What is the cost to the person of changing this behavior?
- Product—What are we selling? Prevention?
- Promotion—How do we reach populations with our message and get their attention?
- Place—Which channels are most appropriate for reaching the target audience? Where are you going to put the message so target audience members will see it?

Ms. Campbell provided examples of social marketing campaigns that have worked and others that have failed. She suggested that it would be important to launch the campaign, evaluate the message and materials, and revise as necessary. She explained the three major behavior models that shape social marketing:

1. The Health Belief Model, which poses the question, “Do you believe you are vulnerable and is there something you can do about it?”
2. Social Learning Theory considers, “What are the barriers to the behavior and what can we do to eliminate or minimize the barriers?”
3. The Theory of Reasoned Action that considers, “What attitudes and beliefs have to be changed before behavior change can take place?”

Ms. Campbell concluded that social marketing requires:

- an understanding of the audience,
- strategic planning from the very beginning,
- targeted distribution--getting the message and materials into venues that the target audience is comfortable with,
- evaluation, and
- patience because it doesn't happen overnight.

A discussion followed the presentation and Ms. Campbell stressed that message development is important. The message must be clear, simple, truthful and culturally relevant. Consideration should be given to socioeconomic factors and variations between different segments of the target audience. The message should be repeated at intervals because health behavior change is incremental.

### *National Kidney Foundation (NKF) Experience*

Dr. Wendy Brown described what the NKF has been doing in terms of minority outreach at the National level and examples of successful programs from affiliates. She reiterated the need for developing collaborative relationships that help to reach target audience members. Healthy People 2010 includes a chapter on kidney disease as a result of many organizations working together to make sure that it was included. She stressed that it takes time to develop such collaborative relationships and while the relationships may start on a national level, it is important for local affiliates of the national organizations to work together to access each target group (African Americans, American Indians, and Hispanic/Latinos).

Another step in developing a successful outreach program and to ensure understanding of the target audience is to include target audience members in planning and implementation of the program. NKF has made an effort to change the composition of affiliate leadership to include members of the target audience and has developed culturally sensitive and language appropriate materials.

### **Examples of successful affiliate programs.**

1. The Program Director at the NKF of Georgia is an African American transplant recipient who spoke and exhibited at a conference of the NAACP. The affiliate gave presentations at churches, senior centers, and Lions Clubs and celebrated at an African American church the birthday of a member's transplant. The community came to the affiliate because of the message and asked to hear more.

2. The NKF of Michigan has a program called “Healthy Hair Starts with a Healthy Body.” They trained 80 stylists to give educational and prevention health chats to their clients while their hair is getting done. They have reached more than 2500 African American women with information about hypertension, diabetes, kidney disease and nutrition. They encourage their clients to get to the doctor if they are at risk. They also collect evaluation data—49% of 440 clients had started a new prevention behavior one month after the health chat, 49% discussed their risk with or saw a doctor, 73% took a preventive step or saw a physician. Six women were diagnosed with diabetes or hypertension. In follow-up phone calls, 93% of those who had adopted a new healthy behavior such as a low-salt diet or walking were still practicing that behavior.
3. NKF of Connecticut has a strong minority outreach program. For the past several years they have held a “Black History Month Reception,” the purpose of which is to educate community leaders about kidney disease.
4. NKF of South and Central Texas developed a “*Día de la Información de la Paciente*” or Patient Information Day that is conducted entirely in Spanish. It includes information about dialysis, nutrition, and transplantation. Nutritionists provide healthy snacks and recipes, so people can prepare healthier versions of their favorite recipes.
5. NKF of Oklahoma sponsored a conference on Diabetes for American Indians that stimulated an interest among various tribes that together formed the American Indian Kidney Conference. The first conference included exhibits, a gospel sing, and a pow-wow and led to three KEEP screenings among the tribes. The second conference (to be held in July) will be called, “Triple Threat: Diabetes, hypertension, and kidney disease. It will include information about the prevention, detection and treatment of all three.
6. This spring at the NKF Spring Clinical Meetings, there will be a nephrology update in Spanish, cosponsored by the Latin American Society of Nephrology and Hypertension, the Argentine Society of Nephrology and the Spanish Society of Nephrology. It’s directed toward practicing nephrologists and primary care physicians. All the lectures and handouts will be in Spanish. The goal is to educate 100 physicians from all parts of the Spanish-speaking world.

Dr. Brown also mentioned that NKF published “*Minority Outreach Update*” which shares other affiliates’ success stories and may be helpful to NKDEP.

A discussion about how to reach physicians followed Dr. Brown’s presentation. Ms. Campbell commented that there are a number of different strategies for reaching physicians including major conferences and meetings, articles in professional journals, peer-to-peer interactions at a local level. Dr. McClellan reported that recent studies show that many traditional methods fail to change physician behavior and that it will be important for NKDEP to activate patients to interact with prepared physicians.

## *Summary of Meeting for Report*

Dr. Hostetter concluded the meeting by highlighting key points of the day's discussions. He asked for general consensus from meeting participants about targeting high-risk populations rather than the general population. Participants discussed the advantages and disadvantages of broad- versus narrow- scope education efforts, including goals, potential target audiences, channels, and evaluation measures.

NKDEP will need to determine where to target within the spectrum of disease. The participants discussed the possibility of developing a "renal risk score" to use as a social marketing tool. There was some agreement that a tool could be developed for lay audiences that would help them decide whether to talk to their doctor about kidney disease and/or ask for a routine urinalysis. Some participants agreed that it would be helpful to have a simple renal risk score to break through patient denial, such as a card with a checklist of risk factors:

- Do you have proteinuria?
- Do you have a creatinine level above 1.5?
- Do you have hypertension?
- Do you have diabetes?
- Do you have a reduced GFR?
- Do you have a relative with kidney disease?

Another participant suggested that it might be appropriate to start with simple messages such as:

1. Have a routine urinalysis done.
2. Protein in urine is bad.
3. Why are kidneys important?

Dr. McClellan supported the idea of a campaign goal to reduce the epidemic of ESRD. NKDEP has the data to define, describe, and segment the high-risk target groups from the USRDS, NHANES, and some of the family studies. He suggested a possible message, "If you are in one of the high risk populations (hypertensives, diabetics, family member with ESRD, or obese), you need to have your kidneys checked on a periodic basis."

To evaluate the program, NKDEP can use:

- BFRSS (a universal population-based assessment on an ongoing basis) and the Medicare PRO system claims data as a process measure to assess whether high risk populations are having their kidneys checked regularly;
- NHANES 2000 as an intermediate health outcome measure, providing prevalence within the population of elevated serum creatinine levels; and,
- USRDS as an outcome measure to determine whether there is an impact in the ESRD epidemic.

The Medicare PRO system can track hospital charts to see if they are receiving proper care. Insurance claims data could be used to measure the number of urinalyses conducted during a certain period of time.

NKDEP also can conduct pilot campaigns in certain communities that are randomly selected and compare them to controls.

Suggestions for collaborative partners included:

- HCFA PROs
- Employer groups
- ESRD Networks
- OCSQ

Dr. Hostetter thanked participants for their work today and asked them to consider what groups might be interested in working with NKDEP in this effort.

March 16, 2001

Dr. Hostetter and Dr. Briggs welcomed participants back for the second day of the meeting and participants introduced themselves.

## **Session I: Optimal Performance Screening**

### *Screening and KEEP 3.0*

Dr. John Flack suggested that screening for CKD is worthwhile because it meets the following criteria:

- There is effective treatment for CKD.
- CKD is a significant clinical and/or public health burden.
- There is a reasonably accurate and simple way to identify risk of CKD.
- The label of risk will do more good than harm (this may or may not be true of CKD).

An accurate classification of kidney function is important because it impacts:

- Use of the Joint National Commission (JNC6) Guidelines.
- Appropriate blood pressure targets (130/85 instead of 140/90).
- Antihypertensive drug selection (incorrect avoidance of diuretic).
- Ancillary drug selection (glucophage or NSAIDs, such as ibuprofen).
- Proper use of ACE inhibitors.
- Decisions about how many and what kind of drugs will be needed to successfully lower blood pressure.
- An attenuated systolic blood pressure response. (Micro- and macro-albuminuria can predict an attenuated systolic blood pressure response.)

Dr. Flack expressed dismay at the evidence that knowledge is not translating into practice in the clinical setting. There are so many guidelines and guideposts provided for physicians who have a very limited amount of time with each patient. Physicians cannot integrate all of the guidelines without automatic system supports.

Dr. Flack described KEEP 3.0, a large prospective high-risk cohort study that will begin this summer. The study will include participants who have been identified as at high risk for kidney disease because they have hypertension, diabetes or a family member who has hypertension, diabetes, or renal disease. Based on what he learned yesterday he may ask the steering committee to include people who are overweight as well. The study aims to determine:

- The prevalence of CKD and risk factors in this cohort;
- The cross sectional association of CKD and risk factors;
- The rate of change of CKD and risk factors (to see which factors influence progression); and
- The long-term morbidity and mortality of this cohort.

KEEP 3.0 is going to try to favorably influence outcome (progression of kidney disease) by providing feedback to patients and physicians to influence medical and personal decisions in a positive direction.

KEEP 3.0 will include a detailed medication history and follow patients longitudinally to study the impact of the medications on the natural history of renal disease. The study will track a number of physiologic measures and bank urine and blood samples for future reference. KEEP 3.0 will:

- Screen high risk individuals,
- Provide feedback about data that is collected,
- Provide counseling and referral, and
- Send information to the physician.

### *Singapore NKF Population Screening*

Dr. Sylvia Ramirez presented an overview of prevention programs in Singapore via telephone hook-up and speaker phone. NKF of Singapore's first goal was to educate the public about ESRD options. An early success was the passage of the Human Organs Transplant Act that presumes consent for organ transplantation unless the individual had objected to it during his or her lifetime. The number of transplants increased.

Before 1987, all dialysis in Singapore was financed by personal funds, so most patients (95%) who needed dialysis were dying. In 1987, the NKFS introduced a program to subsidize renal replacement therapy.

Dr. Ramirez reported that the population in Singapore presented a unique opportunity for a public health education campaign because of the increasing incidence of ESRD and the high prevalence of diabetes in this island nation. She described elements of the program and highlighted lessons for NKDEP:

- Take screening efforts to the target population. For example, they have mobile buses that go to easy-to-access locations—work sites, community centers, schools.
- Go to community leaders to obtain additional funding for education efforts.
- Use all methods of communication, including the media.

### *Therapy*

Dr. Sharon Anderson reported on current optimal treatment for kidney disease based on recommendations from sources listed in the slides. Doctors should anticipate a complication, detect it early, and treat it aggressively. She suggested that screening could be more effective if one considers who is at highest risk.

Dr. Anderson highlighted the following guidelines as particularly relevant to NKDEP:

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- Screening for microalbuminuria (may use spot albumin/creatinine ratio) provides the earliest detectable sign of diabetic renal disease and a marker for increased cardiovascular (CV) as well as renal risk. This test should be done at diagnosis of type 2 diabetes, at 5 years or puberty for patients with type 1 diabetes, and then annually for both groups.
- Screening for proteinuria (not diabetic) and microalbuminuria provides the first detectable evidence of renal disease, a marker for increased CV risk in the general population, and a marker for increased risk of loss of GFR in patients with renal disease.
- The recommended dietary allowance (RDA) of protein for most groups is 0.8g/kg/day. In nondiabetic patients with a GFR of <25 ml/min/1.73 m<sup>2</sup> it is 0.6 g/kg/day.
- For people who have diabetic nephropathy, it is important to avoid known risk factors for acute renal failure, such as: nonsteroidal anti-inflammatory drugs, herbal medicines, inappropriate drug dosing, and prevention of contrast nephropathy.

Dr. Anderson described treatment for diabetic nephropathy, including optimal glycemic control for people who have type 1 and type 2 diabetes. She presented slides showing the advantage of aggressive blood pressure management for people who have diabetes and for people who have nondiabetic renal insufficiency. Other slides showed the importance of using ACE inhibitors for patients with hypertension and renal insufficiency, patients with diabetes, and patients with renal insufficiency. Dr. Andersen also recommended smoking cessation and the use of lipid reduction therapy to reduce CV risk and renal risk, although the evidence for reducing renal risk is epidemiological and not yet conclusive.

## *Discussion*

The discussion following this session focused on pediatric risk assessment. Participants also debated the accuracy of proteinuria as a measure of kidney function. Dr. Hostetter recommended the development of a dipstick that would show the proteinuria to creatinine ratio. (At least one such technique is available.)

Participants also agreed on the need to define a role for PCP's (targeting those who care for diabetics and hypertensives), including recommendations about when to refer to a nephrologist. The KDOQI Guidelines will include information about when to refer to a nephrologist. The need for practical brief guidelines for PCP's was noted.

A representative from the Renal Physicians Association (RPA) stated that the organization is developing guidelines about the use of ACE inhibitors.

Another participant stated that the NKDEP should:

- Prioritize and simplify guidelines.
- Provide an easy-to-use algorithm.
- Use technology to make the diagnosis and treatment of kidney disease easier.
- Couple education efforts with hypertension and diabetes education programs.
- Focus on patients with diabetes and/or hypertension and people who have a first order relative with diabetes, hypertension, or kidney disease.

## Session 2: Current Practice

### *Outpatient Data*

Dr. Brian Pereira presented information from a study of between 4,000 and 5,000 case records from academic medical centers and private practice physicians' offices in the Boston area. He presented information about:

- prevalence and characteristics of CKD patients,
- timing of nephrology referral,
- how patients are tested for co-morbid conditions and complications,
- the prevalence of these complications,
- the frequency and timing of interventions,
- how patients are prepared for renal replacement therapy, and
- resources that are utilized during the phase of CKD.

Most referrals to nephrologists in this study came from PCPs or internal medicine specialists. The creatinine levels for most first visits to the nephrologist were below 3.0, which is earlier than other parts of the country. Since serum creatinine is not a perfect measure for kidney function, the GFR at the time of referral was actually lower than optimal and most of the complications of uremia were firmly established.

Dr. Pereira reported that despite NKF Guidelines, many patients were not receiving optimal care in the Boston area. Forty-nine percent of nephrology patients received ACE inhibitors--65% of diabetic patients and 39% of non-diabetic patients. Only 22 percent were on low-protein diets. Discussion of kidney replacement took place when GFR was less than 20 ml and access was placed at 13 ml. He also mentioned that creatinine level and GFR did not predict the number of hospital or doctors visits. CKD patients use resources even before ESRD—on average, 5.5 visits per year to the doctor and 1 hospital stay for an average of 7 days.

Participants expressed surprise and dismay at the number of patients who were not receiving optimal care in Boston (considered to be a center of best-care practices). A discussion followed Dr. Pereira's presentation and there was general agreement that NKDEP needs to translate current guidelines into practice.

## *The HCFA Perspective on Performance*

Dr. Steve Jencks, Health Care Financing Administration (HCFA) opened his presentation by assuring participants that the story is no different in other parts of the country. Not all patients are receiving optimal care. NKDEP has a national opportunity to improve care. He suggested that it is possible to actively manage quality and that it is important to develop partnerships with all stakeholders, including other major purchasers. To ensure quality care, Dr. Jencks suggested that NKDEP build systems to allow the physician to add judgment and humanity but not make mistakes.

Dr. Jencks provided information about what HCFA does to achieve the desired results:

1. Manage the process in partnership with stakeholders
2. Select priority areas, that is, where there is consensus and where improvements can make a measurable difference
3. Develop performance measures
4. Collect and analyze data
5. Identify improvement opportunities.
6. Select interventions that match a given purchasing strategy
  - Establish and enforce standards
  - Provide technical assistance
  - Use payment and coverage to improve care
  - Give consumers assistance and information, where it is effective
  - Creation of action partnerships
  - Rewards for desired performance
7. Base evaluation and research on process and outcome measures.

He reported the success of the HCFA program with regard to improving hemodialysis and hemoglobin levels after studies showed a need for improvement. Evidence shows that if there is an intervention that works, we can improve care.

Dr. Jencks provided background information about the peer review organizations (PROs). PROs are technical assistance contractors. There is one in every state and their mission is to improve quality and accuracy, and provide beneficiary protection. They are under performance contracts to improve quality statewide. He suggested that NKDEP could work with the PROs given the selection of appropriate priority topics. At the moment they are working on heart attack, heart failure, pneumonia, and stroke on the in-patient side and diabetes, flu and pneumococcal immunization, and mammography on the outpatient side. He suggested that Pros might not be able to take on new work for a while, but currently have some interest in measuring kidney function within the diabetic population.

Dr. Jencks suggested that the U.S. healthcare system needs to change in light of the increasing complexity of medicine and the increasingly available medical technology. He believes that changing the system will make it easier to prevent kidney failure. One way to improve the current system is to have office staff trusted by the physician use systems to implement basic patient care. He urged participants to read the IOM Report, *"Crossing the Quality Chasm."*

### *Using Existing Resources to Determine Patterns of Care for CRI Patients: Medicare's Disease Surveillance System*

Dr. McClellan presented information about the Medicare Disease Surveillance System. He explained how to evaluate patterns of care by using claims data and chart review in the hospital and in ambulatory care settings. Once evaluation is complete, this data can be used to try to improve care.

He described one effort to improve the management of CKD. Baseline data was collected and opportunities for improved care within the hospital were reported to staff. After one year data was collected again. Some hospitals showed a substantial improvement, while others did not. Many doctors discount or ignore hospital-discharge data, thinking that appropriate care is given later in an outpatient setting. Dr. McClellan explained that the Medicare Disease Surveillance System can look at care across settings and that it is not taking place in either setting.

Dr. McClellan described an intervention in Georgia designed to check and improve the adherence to ADA Guidelines in management of diabetic patients. The PRO used Part B claims data to identify patterns of care within various counties in GA. Doctors received feedback reports and education materials. The conclusions relevant to NKDEP are:

- There was some incremental improvement in some areas of care.
- It is possible to track trends in screening and in care.
- Screening can influence outcome. County-specific renal failure rates were inversely related to urine-testing rates.
- Patterns of care varied within the state by county and screening was not as good in counties with large numbers of African Americans.
- Many doctors claimed that patients were not receiving care because they are non-compliant. However, the data shows that diabetic patients in the study group visit the doctor an average of 5.5 times per year and are not receiving the proper screening tests during that same year.
- Comparative practice profiles improved quality of care. Providing the feedback through an interpersonal communication channel increases the likelihood of improved physician performance (academic detailers paid personal visit to physicians).

He concluded that Medicare's Disease Surveillance System is a powerful tool to measure success.

## *Data from USRDS*

Dr. Allan Collins presented data from a USRDS study of current practice and delivery of preventive care to ESRD patients. The study showed that many patients do not receive preventive screening tests or preventive care. There are racial and gender differences. The data show that Native Americans are underserved with regard to all preventive screening tests and that Asians and women are underserved with regard to some preventive tests.

Dr. Collins reported that even patients in the highest risk group are not receiving recommended screening tests. For example, even after an acute myocardial infarction, patients did not receive lipid-screening tests.

The study group also looked at pre-ESRD care (2 years prior) to determine what kind of care patients received before dialysis. Fifty to fifty-three percent saw a nephrologist during the time period, but most of these visits turned out to be hospital consults and not an integrated part of their outpatient care. Only one-third of the population received HDL testing during that time period. Only 14 percent received EPO (erythropoietin) before ESRD.

## *Discussion*

Dr. Briggs asked participants to consider what kind of system-wide changes could be made to improve care. One participant suggested that Medicare data could be used to:

- make problems in the system visible to providers and insurers;
- interest insurers and payers in the problems and solutions;
- encourage providers to back guidelines of care; and
- implement system-wide changes to improve care.

Another participant mentioned that American Medical Association (AMA) guidelines and collaborative efforts preceded other major initiatives that have succeeded.

He recommended that it would be important for NKDEP to:

- Get purchasers to support the guidelines for practice
- Get professional associations and other partners to endorse the same message
- Use data feedback as a part of the campaign
- Develop new system (e.g., standing orders, pathways—don't just exhort and educate)

## Session 3: Strategies for Change

### *High Blood Pressure*

Dr. David Hyman examined hypertension data and the prevalence of people in each of the following groups:

1. unaware that they have high blood pressure
2. aware and untreated
3. treated, but not controlled
4. controlled (approximately 25 percent)

He looked at this data from a number of different perspectives to determine who was in each of the four groups and why. Dr. Hyman suggested that many patients in the first three categories were there for reasons related to physician behavior rather than noncompliance or lack of access to health care.

- Most people in the first three categories do have insurance and access to medical care.
- The unaware hypertensive sees the doctor (on average) 2.3 times per year.
- The aware untreated hypertensive sees the doctor 2.1 times per year.
- The treated, but not controlled hypertensive sees the doctor 6.3+ times per year.

Dr. Hyman suggested that if doctors are not helping a patient control their blood pressure in 6 visits per year, then they might not be trying. However, he explained that high blood pressure treatment in the United States is actually a success story—that treatment of blood pressure has resulted in a decrease in the number of strokes and the decline of heart disease mortality. The reason that the numbers look so bad is because of the definition of control, 140 and 90. In practice, physicians do not hold fast to these numbers and consider age and other variables when deciding how aggressively to treat a patient. The patients in the first three categories actually have blood pressures that are only slightly higher than the definition of normal and many of the patients in the third category were taking non-pharmacological measures to control their blood pressure.

Dr. Hyman stated that the average age of all hypertensives in this country is 59. He also mentioned disparity between racial groups within the four categories.

- Black men are less likely to be unaware of hypertension than whites.
- Young black men are more likely to be treated and controlled than whites.

Recommendations for NKDEP:

- Guidelines alone don't change physician behavior.
- Feedback for physicians (report cards) may help—HEDIS Program may provide an answer, but there may be feedback overload because of the number of areas now being graded. Many primary care offices are not part of a system and are not getting graded in any way.
- Build consensus for change.
- Continue to feed information to the physicians. Repeat messages.
- Focus on primary care physician and provide clear, concise and valid messages.

## *Guideline Initiatives*

Dr. Andy Levey opened his presentation by congratulating NIDDK for starting this initiative. Dr. Levey reported that the NKF expanded its guidelines initiative from the care of dialysis patients to include the care of patients with CKD. The program for dialysis patients was known as DOQI, the Dialysis Outcome Quality Initiative. The new program is KDOQI, Kidney Disease Outcome Quality Initiative. The first step will be to standardize the terminology of kidney disease. The CKD Workgroup goals are to:

1. Classify the stages of CKD.
2. Evaluate the lab measurements for clinical assessment of kidney disease.
3. Associate the level of kidney function with complications of kidney disease.
4. Stratify risk for loss of kidney function and development of CV disease.

Dr. Levey stated the evaluation, treatment, and prognosis of patients with chronic kidney disease and individuals at risk should be guided by the stage of disease presented in the KDOQI Classification of that stage as presented below. The new guidelines will be published later this year.

### **CKD Clinical Action Plan: Guide by Stage of Disease**

Stage		GFR	Action
0	At Risk	> 90	Screen
1	Damage	> 90	Diagnose and treat—no decrease in GFR, but another marker for kidney disease (such as proteinuria)
2	Mild	60-89*	Estimate prognosis
3	Moderate	30-59	Evaluate and Treat Complications
4	Severe	15-29	Prepare for kidney replacement therapy
5	Kidney Failure	< 15 or dialysis	Replacement if uremia present

\*This level may be normal for older individuals, but it is not without consequences. Decreased kidney function may put them at increased risk of adverse outcomes of other diseases or treatment of disease. For example, doses of drugs may need to be reduced.

Dr. Levey explained that having a classification system will:

- Improve communication
- Impart clinical information to our patients
- Inform the public
- Disseminate research results
- Enhance the conduct of research by focusing interventions and efforts at different stages of disease

The Workgroup decided to use GFR to define the level of kidney disease because:

- creatinine is only a marker of kidney function, and
- people are familiar with the concept that the kidney is a filter.

GFR indicates how well the kidneys are able to filter and a decrease in the GFR means a decrease in ability to filter. NKF will follow other educational models by insisting that physicians and patients “know their number.” The goal is to increase the total GFR for the U.S. population.

Dr. Levey also presented data about the prevalence of each stage of kidney disease. Given this data, it is clear that chronic kidney disease is an enormous public health problem.

Dr. Briggs expressed concern that Stage 2 may incorrectly identify and label people as having kidney disease when they do not.

### *Capitated Efforts in Progression*

Dr. John Dickmeyer, RMS Disease Management (RMS), Inc, Baxter Health Care, reported on RMS's success in managing chronic kidney disease.

He explained that it is hard to convince payers to spend additional dollars on the early care of kidney disease patients unless they know that there will be a decrease in costs in the long- or the short-term. Commercial health plans tend to look at costs on a quarterly basis and are not swayed by cost-savings that are five years in the future.

RMS signed contracts that guaranteed a discount in historic costs with several health plans, including Humana, Florida Medicaid, Blue Cross in Kentucky and a small plan in California. At this point, outcomes have improved and costs have decreased. RMS helped the health plans look at the outcomes of single providers and improve the systematic approach to care.

Opportunities for improvement among ESRD patients included:

- Decrease the number of hospital days
- Decrease the number of ER visits (ER visits not related to a hospitalization have decreased dramatically)

RMS also created EPO efficiency and developed a patient satisfaction instrument (more than 95% of their patients are satisfied with the program).

RMS is now working to improve the care of patients with chronic kidney disease as well.

The company uses a nurse-driven model with nephrology leadership. The nurses are called Health Service Coordinators (HSCs). HSCs have a substantial amount of ESRD experience and they are trained to handle 80 to 100 ESRD patients and 250 patients with renal insufficiency. The medical management process is managed with software designed for this purpose. The HSC:

- Does an initial patient assessment in the patient's home
- Develops a care plan with the nephrologist that addresses individual patient needs
- Implements the care plan—patient education with an agenda for each patient to take to their doctor based on guidelines of care and the assessment process
- Collects outcome data
- Meets with the doctors and health plan coordinators on a quarterly basis—quality improvement committee.

Dr. Dickmeyer explained that their focus has been co-morbidity management and showed evidence of their success in improving a variety of outcome measures.

The RMS Medical Management Model for CRI is almost the same as the one described above. The most challenging aspect of this protocol is finding the patients. This intervention is just getting started and Dr. Dickmeyer described some of the methods they are using to find the patients. The program is guideline driven and is based on three

stages of renal insufficiency and four areas of care—physical and emotional assessment, laboratory results, self-management and the necessary interventions at each stage. The emphasis is on early detection to:

- identify and minimize the co-morbidity of diabetes, hypertension, anemia, and cardiovascular disease,
- prepare for renal replacement therapy--early referral, the modality choice, access prior to initiation of dialysis, and
- retard progression of kidney disease.

RMS will be tracking this population to demonstrate a change in the progression of kidney disease.

Some discussion followed Dr. Dickmeyer's presentation. Participants asked how PCPs and patients have received the program. The primary care physicians continue to monitor these patients with the help of the HSC and receive an outline of support from the nephrologist once or twice a year in stages 1 and 2 respectively. In stage 3, the PCPs agree that the care is too complex and belongs in the hands of the nephrologists. The patients benefit from the interpersonal contact with the HSC and the HSC acts as an advocate for the patient and the family. The nurses are expected to sit down to a meal with the family once every couple of months.

### *CQI/QA and Beyond Guidelines*

Dr. Alan Kliger presented information about clinical practice guidelines, including a general definition, "Systematically developed statements based on current professional knowledge to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances." There has been a proliferation of guidelines. There are more than 1,500 guidelines covering the core of what nephrologists do.

He also defined the attributes of good performance measures. They are:

- Derived from evidence-based Practice Guidelines
- Measures of the clinical encounter
- Actionable by a clinician
- Precisely defined
- Collectable
- Tested: validity, sensitivity, specificity, reliability, reproducibility

He showed how three specific guidelines have helped to measure professional performance and to improve care. One thing that has contributed to the improvement in care is feedback given to physicians and hospitals. There is a system in place that has worked in conjunction with the feedback. Nurses within the dialysis units give the message back to patients to change their EPO doses and their iron doses.

Another benefit of performance data can be derived by comparing outcome measures across networks and identifying best practice models to further improve performance. One can use performance measures to consider variation between groups and in different parts of the country and to then work toward further improvement. For example, women, older people, minorities, and people with diabetes are less likely to have an AV fistula as access (the preferred method).

Dr. Kliger also showed that the level of albumin has not changed over time despite measurement and feedback efforts by physicians. He submitted that this is because albumin is an area that is not actionable by a physician.

He concluded that clinical performance guidelines and clinical performance measures improve outcomes by:

- Providing a benchmark and feedback
- Capturing the attention of the physician and the patient with facility-specific outcome reporting to HCFA
- Submitting results to an oversight agency
- Reporting facility-specific information about performance and outcome to the public
- Encouraging and enabling continuous quality improvement (CQI)

Dr. Kliger recommended that NKDEP should:

- Select outcomes that measure the clinical encounter and are “actionable.” For example, those that have to do with heart disease, diabetes control, measures that change the progression of renal failure.
- Continue facility- and practitioner-specific feedback
- Benchmark best facilities and best practitioners to serve as examples and advise
- Teach and support CQI on a local level

### *Discussion*

A discussion followed Dr. Kliger’s presentation. One participant suggested that it would be important for NKDEP to consider where to invest time and energy—what will provide the most improved outcome for the effort. Another suggested that it is important to consider the patient side in the decision-making process and that patients should be included in the guideline-developing process.

Dr. Hostetter thanked participants and adjourned the meeting.